HEALTH AND SENIOR SERVICES

SENIOR SERVICES BRANCH

DIVISION OF SENIOR BENEFITS AND UTILIZATION MANAGEMENT

Proposed Amendments: N.J.A.C. 8:83-2.1 and 6.9; and 8:83D-2.1, 5.6,

6.9, and 6.11

Pharmaceutical Assistance to the Aged and Disabled Eligibility Manual Definitions: Authorization

Senior Gold Prescription Program Manual Authorization; Definitions; Responsibilities in the Application Renewal Process; Confidentiality and Disclosure of Information

Authorized By: Fred M. Jacobs, M.D., J.D., Commissioner, Department of Health and Senior Services.

Authority: N.J.S.A. 30:4D-20 et seq., particularly 30:4D-24; Executive

Reorganization Plan No. 001-1996; and N.J.S.A. 30:4D-43 et seg.,

particularly 30:4D-45.

Calendar Reference: See Summary below for explanation of exception to

calendar requirement.

Proposal Number: PRN 2006-52.

Submit written comments by April 22, 2006 to:

Kathleen Mason, Acting Deputy Commissioner Senior Services Branch Department of Health and Senior Services PO Box 715 Trenton, NJ 08625-0715

The agency proposal follows:

Summary

The Department of Health and Senior Services is responsible for administering the Pharmaceutical Assistance to the Aged and Disabled (PAAD) program pursuant to N.J.S.A. 30:4D-20 et seq., and Executive Reorganization Plan No. 001-1996. The Department is responsible for administering the Senior Gold Prescription Discount Program (Senior Gold program) pursuant to the Senior Gold Prescription Discount Act, N.J.S.A. 30:4D-43 et seq.

The PAAD program provides prescription discounts to certain elderly and disabled New Jersey residents. The Department administers the PAAD program by means of the PAAD Eligibility Manual at N.J.A.C. 8:83. The Senior Gold program assists New Jersey residents who have significant needs for prescription drugs and/or other pharmaceutical supplies and are unable to meet fully the costs of such items, but whose level of income disqualifies them for benefits under the PAAD program. The Department administers the Senior Gold program through the Senior Gold Prescription Program Manual at N.J.A.C. 8:83D.

In 2004, the Department adopted amendments to the PAAD Eligibility Manual to enable the Department to coordinate the benefits provided under the PAAD program with benefits available under the Medicare Prescription Drug Program, established pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, 117 Stat. 2066, approved December 8, 2003, available at http://www.cms.hhs.gov/mmu/HR1, and the regulations promulgated thereunder by the Centers for Medicare and Medicaid Services (CMS) at 42 CFR §403.800 et seq., available at http://www.cms.hhs.gov/mmu/regulations/default.asp. See 36 N.J.R. 3619(a) (August 16, 2004), 36 N.J.R. 5682(b) (December 20, 2004); and 36 N.J.R. 2602(a) (June 7, 2004), 37 N.J.R. 281(a) (January 18, 2005).

The Department proposes to amend the definition of CMS at N.J.A.C. 8:83-2.1 to delete reference to the former name of CMS, HCFA. The Department believes that the regulated community has become accustomed to using the new name and the transitional period during which forms referencing "HCFA" were being updated to refer to "CMS," for the most part is over.

As described below, the Department proposes similar amendments to the Senior Gold Prescription Program Manual at N.J.A.C. 8:83D-2.1, 5.6, and 6.11 that likewise would enable the Department to coordinate the benefits provided under the Senior Gold Prescription Discount Program with benefits available under the Medicare Prescription Drug Program.

The Department proposes to add the following definitions at N.J.A.C. 8:83D-2.1: "authorized representative," "'Centers for Medicare and Medicaid Services' or 'CMS,'" "Medicare-approved prescription drug discount card program," and "Medicare Prescription and Drug Program." The term "authorized representative" would track the language defining that term at 42 CFR §403.802, except to the extent that the Federal language enables an "authorized representative" to make healthcare decisions on behalf of the represented person, as the Department only intends to take responsibility for negotiating with the Federal government the coordination of represented persons' benefits. The term "CMS" would track the definition provided with respect to PAAD, as proposed for amendment described above. The term "Medicare-approved

prescription drug discount card program," a term proposed for use at new N.J.A.C. 8:83D-6.11(c)9, would mean a prescription drug discount card program as to which the sponsor thereof has received Medicare approval and has entered into a contract with CMS.

As at N.J.A.C. 8:83-5.6(c)1ii with respect to the PAAD program, the Department proposes to amend N.J.A.C. 8:83D-5.6(b)1ii to specify that necessary evidentiary documents that applicants and beneficiaries are responsible to submit in support of an application for Senior Gold benefits include copies of third party health insurance cards and Medicare prescription benefits coverage cards, to the extent applicable.

Existing N.J.A.C. 8:83D-6.11(a) prohibits the release of personally identifiable information regarding applicants and beneficiaries obtained or maintained by the program and requires the Department to hold that information in confidence, unless the applicant or beneficiary, or his or her authorized agent authorizes the disclosure in writing. Existing N.J.A.C. 8:83D-6.11(b) permits disclosure of such information without the consent of the applicant or beneficiary, or his or her authorized agent, for purposes directly connected with the administration of the program pursuant to State law and regulations. Existing N.J.A.C. 8:83D-6.11(c) exempts from the requirement of written authorization certain disclosures. As it did at N.J.A.C. 8:83-6.11(c) with respect to the PAAD program, the Department proposes to amend N.J.A.C. 8:83D-6.11(c) to add new paragraph (c)9, which would exempt from the requirement of written authorization the disclosure of personally identifiable information pertaining to an applicant or beneficiary for the coordination of benefits under the Senior Gold program with benefits available under the Medicare Prescription Drug Program.

The Department proposes amendments to both the PAAD program at new N.J.A.C. 8:83-6.9(a)1 and the Senior Gold program at new N.J.A.C. 8:83D-6.9(a)1 to establish that in executing an application or renewal form, as applicable under the circumstances, an applicant or re-applicant for benefits under these respective programs authorizes the Department to serve as the "authorized representative" of the executing person.

As the Department has provided a 60-day comment period for this notice of proposal, this notice is excepted from the rulemaking calendar requirement pursuant to N.J.A.C. 1:30-3.3(a)(5).

Social Impact

The proposed amendments would enable the Department to coordinate benefits between the State-funded prescription assistance programs and the Federal Medicare Prescription Drug Program. The proposed amendments would accomplish this by allowing the Department to obtain necessary documentation from PAAD and Senior Gold program applicants, reapplicants, and beneficiaries

and to share that information as necessary to coordinate benefits. The proposed amendments would also accomplish this by enabling applicants, reapplicants, and beneficiaries to designate the Department as their authorized representative in negotiations with the Federal government.

As of 2004, there were approximately 200,000 PAAD program enrollees and 29,000 Senior Gold enrollees who are potentially eligible for benefits under the Medicare Prescription Drug Program. Thus, enabling the Department to serve as these persons' representative to Medicare would streamline the coordination of benefits process and alleviate the administrative and paperwork burdens that self-administered coordination of benefits would impose on these persons.

Economic Impact

The Senior Gold program at N.J.A.C. 8:83D-6.5 requires the State to be the payor of "last resort" for the benefits provided under the program.

The Department anticipates that the proposed amendments would enable the Department to reduce PAAD program and Senior Gold expenditures beginning in Fiscal Year 2006, by establishing the Medicare Prescription Drug Program drug coverage as primary coverage for the benefits provided under these otherwise wholly State-funded programs. Inasmuch as the establishment of the particular terms of the Medicare Prescription Drug Program is in a transitional period involving negotiation with all the states, potential savings to the State are presently not susceptible to reliable estimation.

Federal Standards Statement

The rules at N.J.A.C. 8:83 and 8:83D establish the administrative manuals for the PAAD and Senior Gold programs, respectively. The proposed amendments would enable the Department to coordinate the benefits afforded under these State-funded programs with the benefits available under the Medicare Prescription Drug Program, established pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, effective December 8, 2003, available at http://www.cms.hhs.gov/mmu/HR1, and the regulations promulgated thereunder by the Centers for Medicare and Medicaid Services at 42 CFR §403.800 et seq., available at http://www.cms.hhs.gov/mmu/regulations/default.asp. To effectuate this coordination of benefits, the proposed amendments would establish a definition of the term "authorized representative" that is consistent with that term as defined at 42 CFR §403.802.

The Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, and the regulations promulgated thereunder by the United States Secretary of Health and Human Services at 45 CFR Parts 160 and 164, known as the "Standards for Privacy of Individually Identifiable Health Information," hereinafter collectively referred to as "HIPAA," apply to health information created or maintained by health care providers who engage in certain electronic transactions, health plans, and health care clearinghouses. The Department's PAAD and Senior Gold programs may be covered entities, specifically, health plans, within the meaning of HIPAA.

Pursuant to <u>45 CFR §164.512(d)</u>, a covered entity may disclose protected health information to a health oversight agency (such as CMS) for oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of the health care system, government benefit programs for which health information is relevant to beneficiary eligibility, entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards; or entities subject to civil rights laws for which health information is necessary for determining compliance.

Moreover, pursuant to <u>45 CFR §164.514(d)(3)(iii)(A)</u>, when making disclosures permitted under <u>45 CFR §164.512</u>, a covered entity may reasonably rely on the representation of a public official that the information requested is the minimum necessary for the stated purpose.

Therefore, the disclosure of PAAD and Senior Gold applicant, reapplicant, or beneficiary information protected under HIPAA to CMS and its endorsed agents, for the purpose of coordination of benefits between the Medicare Prescription Drug Program and the PAAD and Senior Gold programs, would not constitute a violation of HIPAA. To the extent the PAAD and Senior Gold programs may be subject to HIPAA, the proposed amendment at N.J.A.C. 8:83D-6.11(c)9 would meet but not exceed the requirements of HIPAA.

Except as described above, there are no Federal standards applicable to the subject matter of the proposed amendments.

Jobs Impact

The proposed amendments would not have any impact on the gain or loss of jobs in the State.

Agriculture Industry Impact

The proposed amendments would have no impact on the agriculture industry in the State.

Regulatory Flexibility Statement

The proposed amendments would not impose reporting, recordkeeping, or compliance requirements on small businesses, as that term is defined by the New Jersey Regulatory Flexibility Act, N.J.S.A. 52:14-16 et seq. The proposed amendments impose eligibility and application requirements on individuals, none of which are small businesses. Therefore, a Regulatory Flexibility analysis is not required.

Smart Growth Impact

The proposed amendments would have no impact on the achievement of smart growth or implementation of the State Development and Redevelopment Plan.

Full text of the proposal follows (additions indicated in boldface **thus**; deletions indicated in brackets [thus]):

CHAPTER 83

PHARMACEUTICAL ASSISTANCE TO THE AGED AND DISABLED ELIGIBILITY MANUAL

8:83-2.1 Definitions

The following words and terms, when used in this chapter, shall have the following meanings unless the context clearly indicates otherwise:

"Centers for Medicare and Medicaid Services [(]" **or** "CMS[)]" means the agency of the Federal Department of Health and Human Services [which] **that** is responsible for the administration of the Medicare program in the United States. [CMS was formerly known as the Health Care Financing Administration (HCFA).]

8:83-6.9 Authorization

- (a) By signing [/] **or** marking the certification and authorization statement on [the] **an** application [/] **or a** renewal application form, [the] **an** applicant [/] **or a** reapplicant authorizes:
 - 1. The Department to serve as the authorized representative of the applicant or reapplicant;

Recodify existing 1.-4. as **2.-5.** (No change in text.)

CHAPTER 83D

SENIOR GOLD PRESCRIPTION PROGRAM MANUAL

8:83D-2.1 Definitions

The following words and terms, when used in this chapter, shall have the following meanings unless the context clearly indicates otherwise:

"Authorized representative" means a person with legal authority to act on behalf of an individual in making decisions related to the individual's enrollment in, disenrollment from, and access to negotiated prices under the Medicare Prescription Drug Program as defined by 42 CFR §403.802.

"Centers for Medicare and Medicaid Services" or "CMS" means the agency of the Federal Department of Health and Human Services that is responsible for the administration of the Medicare program in the United States.

"Medicare-approved prescription drug discount card program" means a prescription drug discount card program as to which the sponsor thereof has received Medicare approval and has entered into a contract with CMS.

"Medicare Prescription Drug Program" means the program established under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, 117 Stat. 2066, approved December 8, 2003.

8:83D-5.6 Responsibilities in the application renewal process

- (a) (No change.)
- (b) The applicant or beneficiary has the responsibility to:
 - 1. Complete the Senior Gold eligibility application[/] **or the** renewal application form[(s)] legibly and accurately by:
 - i. (No change.)
 - ii. Presenting all necessary evidentiary documents, including a copy of any third party health insurance cards and/or Medicare prescription benefits coverage cards;

iii.-v. (No change.)

2.-10. (No change.)

8:83D-6.9 Authorization

- (a) By signing [/] or marking the certification and authorization statement on [the] a Senior Gold eligibility application [/] or a renewal application form, [the] an applicant [/] or a reapplicant authorizes:
 - 1. The Department to serve as the authorized representative of the applicant or reapplicant;

Recodify existing 1.-4. as **2.-5.** (No change in text.)

8:83D-6.11 Confidentiality and disclosure of information

- (a)-(b) (No change.)
- (c) The prohibition of (a) above against unauthorized disclosure shall not be construed to prevent:
 - 1.-6. (No change.)
 - 7. The release of information or files to county welfare agencies for the purpose of determining eligibility for Medicaid benefits or for subsequent verification of Medicaid eligibility; [or]
 - 8. The release of information or files to the Division of Motor Vehicles in the Department of Law and Public Safety for the implementation of the Fair Automobile Insurance **Reform** Act of 1990 (P.L. 1990, c.8)[.]; **or**
 - 9. The release of beneficiary information or files to Medicare-endorsed prescription drug discount card programs or the Centers for Medicare and Medicaid Services for the purpose of coordination of benefits between the Medicare Prescription Drug Program and Senior Gold.